

### Remarks

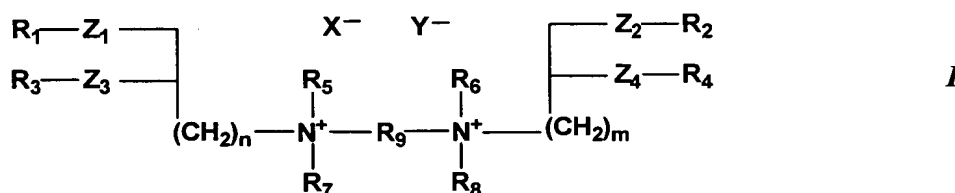
Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 47-94 are pending in the application, with 47 and 83 being the independent claims. Claims 1-46 are sought to be canceled without prejudice to or disclaimer of the subject matter therein. New claims 47-94 are sought to be added. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicant respectfully requests that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

### Description of the Invention

The present invention is directed to particular cationic compounds, compositions comprising said cationic compounds, methods of using said cationic compounds, and pharmaceutical kits comprising said cationic compounds. Specifically, the cationic compounds of the present invention are cationic dimers having the following formula:



wherein  $\text{R}_1$ - $\text{R}_9$ ,  $\text{Z}_1$ - $\text{Z}_4$ ,  $n$ ,  $m$ ,  $\text{X}^-$  and  $\text{Y}^-$  are defined therein. The cationic dimers of the present invention are useful for, *inter alia*, enhancing the delivery of biologically active compounds to a cell. More particularly,  $\text{R}_9$  is a linker moiety which is selected from a group of moieties as described in the present patent application.

***Preliminary Amendment of Claims***


New claims 47-69 are directed to cationic compounds of Formula I. New claims 47-69 are directed to the same compounds as described in original claims 1-23, with the exception that the linker, R<sub>9</sub>, is not C<sub>3</sub>-C<sub>20</sub> unsubstituted alkyl. This amendment is made to distinguish the present invention from compounds that appear to be disclosed in Bhattacharya *et al.*, *Chem. Commun.* (23):2287-2288 (1997). Bhattacharya was cited in a Second Supplemental Information Disclosure Statement, filed November 29, 2000. A copy of Bhattacharya *et al.* is submitted herewith for the Examiner's convenience. Support for new claims 47-69 can be found throughout the application, in particular from page 6, line 10, to page 7, line 4; page 9, line 20, to page 12, line 30; page 28, line 18, to page 30, line 22; and page 36, line 1, to page 39, line 17, of the originally filed application.

New claims 70-78 are directed to compositions comprising a cationic compound. Support for new claims can be found throughout the application, in particular at page 7, line 5-19; page 8, lines 3-11; page 9, line 11, to page 14, line 21; page 16, line 16, to page 20, line 31; page 25, line 20, to page 21, line 18; page 30, line 23, to page 31, line 30; and page 36, line 1, to page 40, line 15, of the originally filed application.

New claims 79-82 are directed to methods of using the cationic compounds of the present invention. Claims 79-82 correspond to canceled claims 28-31. Support for claims 79-82 can be found throughout the application, in particular at page 17, line 1, to page 20, line 31; page 23, line 18, to line 25, line 19; and page 32, line 1, to page 35, line 6.

New claims 83-94 are directed to pharmaceutical kits comprising the cationic compounds of the present invention. Claims 83-94 correspond to canceled claims 32-46. Support for claims 83-94 can be found throughout the application, particularly from page 26, line 19, to page 27, line 24.

Applicant respectfully requests entry of the foregoing amendment prior to any substantive examination of the application on the merits. Applicant believes that the above amendment will be received in the Office on or before the mail date of the first Office Action under 37 C.F.R. § 1.104. Thus, the above amendment is a preliminary amendment. 37 C.F.R. § 1.115.



Applicant asserts that the preliminary amendment will not unduly interfere with the preparation of the first Office Action in the present application. New claims 47-69 are added to claim the cationic compounds *per se*. With one minor exception as noted above, new claims 47-69 are directed to the same compounds as described in original claims 1-23. In addition, new claims 47-69 have been added to emphasize the unity of invention that is present for the compounds of the present invention. As presently drafted, new claims 47-69 are directed to a single genus of cationic compounds in which the linker, R<sub>9</sub>, is selected from a group of structurally related chemical moieties.

In view of the above comments, Applicant respectfully requests entry and examination of the Preliminary Amendment.


### ***The Restriction Requirement***

The Examiner requires restriction to one of three groups of inventions, Groups **I-III**, under 35 U.S.C. § 121.

Applicant hereby provisionally elects to prosecute the invention of Group **I**, represented by originally filed claims 1-20 and 24-46. Group **I** is now represented by new claims 70-73 and 76-94. This election is made without prejudice to or disclaimer of the other claims or inventions disclosed.

This election is made **with** traverse.

In support of the Restriction Requirement, the Examiner stated that Groups **I-III** are distinct for reasons detailed below and have acquired a separate status in the art because of their recognized divergent subject matter. With respect to Groups **I** and **II**, the Examiner states that the composition of Group **I** is of materially separate and different structure than the composition of Group **II**. With respect to Groups **I** and **III**, the Examiner alleges that the method of delivering a biologically active agent to an animal cell requires materially different and separate protocols than the method for delivering a biologically active agent to a plant cell. With respect to Groups **II** and **III**, the Examiner alleges that "the composition and kit in Invention **II** is [sic] not required for the method for delivering a




biologically active agent to a cell of a plant of Invention **III**, and vice versa." The Applicant respectfully traverses the requirement for restriction.

The test for proper joinder of invention within a claim is whether unity of invention exists. Unity of invention exists for compounds when the compounds share a common structural core and share a community of properties, such that the grouping of such compounds together is not repugnant to principles of scientific classification. *In re Harnisch*, 206 USPQ 300, 305 (CCPA 1980). Different classification or provisos are not sufficient conditions to require restriction. Nor is whether "art which may anticipate or render obvious one of the groups would or would not necessarily do the same for those remaining." *In re Harnisch*, 206 USPQ 300, 305 (CCPA 1980).

Further, restriction practice is not applicable to a single claim. *In re Weber*, 198 USPQ 332 (CCPA 1978), *In re Haas*, 198 USPQ 334 (CCPA 1978). These cases make it clear that 35 U.S.C. § 121 does not grant to the U.S. Patent and Trademark Office (PTO) the authority to refuse to examine a single claimed invention. Section 121 only applies to plural claimed inventions in different claims, wherein the different claims vary not just in scope but also in the invention to which each is directed.

Groups **I** and **III** are both directed to the invention of original claims 1-20 and 24-26. Therefore, restriction between Groups **I** and **III** is improper since restriction within a claim is improper. Applicant respectfully requests that Groups **I** and **III** be considered together.

Additionally, Applicant asserts that the restrictions between Groups **I** and **II** and between Groups **II** and **III** are improper. The Examiner stated that the cationic compound of Group **I** is of materially separate and different structure than the cationic compound of Group **II**. Applicant asserts that the compounds of the two groups are structurally related and very similar. Unity of invention exists for compounds when the compounds share a common structural core and share a community of properties, such that the grouping of such compounds together is not repugnant to principles of scientific classification. *In re Harnisch*, 206 USPQ 300, 305 (CCPA 1980). Different classification or provisos are not sufficient conditions to require restriction. Nor is whether "art which may anticipate or render obvious one of the groups would or would not necessarily do the same for those remaining." *In re Harnisch*, 206 USPQ 300, 305 (CCPA 1980).



The compounds of Groups I and II share a common structural core in that the compounds are cationic dimers in which the two quaternary nitrogen groups are connected by a linker. In Group I, the linker comprises, *inter alia*, a ureyl moiety. In Group II, the linker comprises a bis-ureyl moiety. One of ordinary skill in the art would consider these two chemical moieties structurally very similar. In addition, the compounds of Groups I and II share a community of properties in that both the ureyl-containing and the bis-ureyl-containing compounds are useful as transfection agents. Therefore, Applicant believes that restriction between Groups I and II is improper. Furthermore, restriction between Groups II and III is improper for the same reasons as stated for Groups I and II.

Thus, Applicant submits that, in the present case, restriction to one of three groups of inventions is improper. In view of the Preliminary Amendment, Applicant requests that the Examiner consider for examination new claims 47-69, directed to compounds of Formula I, in addition to new claims 70-94, directed a composition, a method, and a pharmaceutical kit. New claims 47-67 are directed to compounds described in original claims 1-20. New claims 47, 58, 68, and 69 are directed to compounds described in original claims 21-23.

However, if the Examiner concludes that the Restriction Requirement is proper, Applicant respectfully requests that the Examiner consider the following group for examination: claims 47-67, 70-73, and 76-94, directed to a cationic lipid compound, a composition comprising said cationic lipid compound, a method for delivering a biologically active agent to an animal cell, and a kit containing said cationic lipid compound.

#### ***Other Matters***

Applicant respectfully requests that all further correspondence in the present matter be directed to the undersigned. On August 11, 2000, Robert H. Zaugg, representative of the Assignee, executed a Revocation of Prior Power of Attorney, Appointment of New Attorneys of Record, and Change of Correspondence Address ("Revocation"). The Revocation appointed new attorneys, including the undersigned, and requested that all correspondence be sent to the undersigned's address. On August 17, 2001, the undersigned

filed the Revocation in the U.S. Patent and Trademark Office. Applicant respectfully directs the Examiner's attention to a copy of the Revocation, along with a stamped return postcard, attached herewith.

The undersigned has also filed in the PTO several items for the present matter. The following items have been filed: 1) Supplemental Declaration for Patent Application, filed August 23, 2000; 2) Information Disclosure Statement, filed August 25, 2000; 3) First Supplemental Information Disclosure Statement, filed September 25, 2000; 4) Corrected Assignment, filed October 11, 2000; 5) Second Supplemental Information Disclosure Statement, filed November 29, 2000; and 6) Third Supplemental Information Disclosure Statement, filed August 9, 2001. Applicant kindly requests that the Examiner acknowledge that each of the aforementioned items has been received and considered by the Office.

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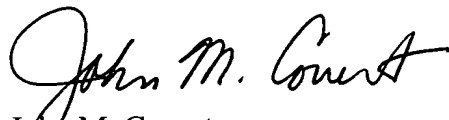
***Conclusion***

All of the stated grounds of objection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all presently outstanding objections and that they be withdrawn. Applicant believes that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



John M. Covert  
Attorney for Applicant  
Registration No. 38,759

Date: Jan. 22, 2002

1100 New York Avenue, N.W.  
Suite 600  
Washington, D.C. 20005-3934  
(202) 371-2600